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VIA MESSENGER

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: REQUEST FOR ADVISORY OPINION

Dear Sir/Madam:

The undersigned submits this request for an advisory opinion of the Commissioner of Food and Drugs with respect to Food and Drug Administration ("FDA") limitations during inspection of or inquiries to device manufacturers whose facilities are located outside the jurisdiction of the United States ("U.S.") government and who distribute devices to the U.S. and other countries.

A. Issues Involved.

Since prior to the passage of the Medical Device Amendments of 1976 (P.L. 94-295), the FDA has conducted inspections of non-U.S. device manufacturing facilities when the manufacturer of a device intended for export to the U.S. consents to such inspection in advance and consistent with any applicable provisions of law in the country where the manufacturer's facilities are located. The manufacturer may manufacture a similar device for which the manufacturer may assign a comparable designation (*e.g.*, model number, trade name, etc.) for the device[1] that is intended for distribution to countries other than the U.S. Each of these devices, for reasons that are to be explained, do not enter into or affect "interstate commerce" as that term is defined in the Federal Food, Drug, and Cosmetic Act (the "FFDCA"), 21 U.S.C. § 301 et seq. The authority of the FDA to apply its resources to enforce compliance with the FFDCA is

[1] Although non-U.S. manufactured devices may be available internationally by the same name and/or model number, in the context of this request FDA jurisdiction is to be determined on the basis of whether the individual device is intended for and does enter into any U.S. state or territory for use as a device.

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directly related to movement or possible movement of a device in interstate commerce. Irrespective of the designation for the device, if it is neither imported into the U.S., held for possible shipment in interstate commerce, nor distributed in interstate commerce, the FDA has no jurisdiction over such devices.

Consequently, any device that is not manufactured in any "state" or "territory" as defined in the FFDCA and not distributed to the U.S. is not subject to the jurisdiction of the FDA. For example, a device that is manufactured in another country, but not distributed in the U.S., cannot be seized or subject to a request for injunctive relief. Because of this fact, no provision of the FFDCA or any regulation promulgated under the authority of the FFDCA is applicable to devices which do not enter into U.S. interstate commerce. Yet, in particular during inspection of international device manufacturers, the authority of FDA inspectors relating to production of information about devices that are not in U.S. interstate commerce is not made clear to such manufacturers.

The undersigned files this request that FDA issue an advisory opinion in the affirmative to the following questions of law:

1. Any device that is manufactured and distributed for intended use outside the U.S. irrespective of any similarity to a device intended for use in the U.S. is not subject to the jurisdiction of the FDA, and information about such device is not required to be provided to the FDA either through FDA inquiry to or inspection of the manufacturer located outside the U.S.

2. During FDA inspection of a device facility located in another country, the FDA representative is not authorized to request and any facility representative is not required to provide any information about manufacture and commercial distribution of any device that is neither intended for nor delivered into the U.S.

3. FDA has no authority to require the production of information relating to the use of any device for which there has been no evidence of U.S. interstate commerce.

4. Neither voluntary disclosure nor nondisclosure in and of itself by any representative of the manufacturer of information related to that manufacturer's device manufactured and distributed outside the jurisdiction of the FDA shall be the basis for denial of import entry of such device into the U.S.

B. Statement of Facts and Law

Facts:

Device manufacturers located outside of the United States (U.S.) which manufacture and distribute a device intended for import into the U.S. may manufacture and distribute the same or similar type of device to users in countries other than the U.S. However, the device composition, labeling/advertising, and use methods/conditions for

other countries may differ significantly from the device that is exported to the U.S. for distribution in the U.S.

Some of the differences related to the device present in the U.S. and other countries include but are not limited to:

1. labeling or advertising documents that are expressed in a different language or have different content including indications/instructions for use, warnings, cautions, etc.;

2. design features that are different;

3. over-the-counter ("OTC") versus prescription/restricted use differences;

4. licensed practitioners uses and licensure criteria requirements that differ, *e.g.*, physician education/licensure maintenance; physician versus nurse practitioners or lay person; user level of sophistication/education between rural and urban environment; unique regulatory options/restrictions, etc.;

5. differences in practice of medicine;

6. different user disclosure/confidentiality opportunities/restrictions;

7. differences in target population demographics, coexisting conditions, and coexisting therapeutic and diagnostic modalities (*e.g.*, drug therapy); and,

8. different country laws/regulations.

These various differences and combinations of differences may affect the ultimate performance characteristics/expectations of the device which prevent or significantly affect any possibility of country to country comparisons. This is particularly applicable to user experience expectations and results.

Apart from factors that relate to use of the device, conditions relating to manufacture, storage, end of life expectations, and distribution methods may affect the possibility to apply any post market evaluation comparison between the experience associated with use of the same or similar device in the U.S. as opposed to that of another country. Additionally, in the absence of any recognized treaty or memorandum agreement, it is essential to recognize the right of a manufacturer to protect and safeguard from disclosure information to different government agencies for which information about the device is not related to experience with such device in that country.

It is a fact that during FDA inspections of device facilities outside the U.S., FDA inspectors have been directed to demand production of information, *e.g.*, complaints, that

relate to use of devices that are used in other countries and for which there is no evidence to demonstrate that such device is or ever has been in U.S. interstate commerce.

Failure to provide such information for devices that have neither been nor are distributed in the U.S. has resulted in import detention or threats of detention by the FDA.

It is the position of the undersigned that under the facts described above, representatives of the FDA do not have lawful authority to demand production of information through inquiry (*e.g.*, telephone, correspondence including e-mail, or through any third party including but not limited to non-U.S. government representatives) or physical inspection of a facility located outside of the U.S. Moreover, notwithstanding the possibility that representatives of the FDA may make such requests for information about non-U.S. distributed devices (*e.g.*, medical device reports), those to whom such requests are directed have a right to decline and expect that the FDA will not apply any sanction, *e.g.*, import detention/alert, because of the right of such person to decline the FDA request.

The principal objective of this request for "Advisory Opinion" is to confirm that FDA jurisdiction over the development, manufacture, distribution and/or use of a device is restricted to devices for which commercial distribution in "interstate commerce" of such devices has been established as a matter of fact and law.

As required pursuant to 21 C.F.R. § 10.85(b) the statement of law follows.

Law

The formation of the United States of America ("U.S.") and the establishment of the Constitution created a system of government that was intended to provide rights, responsibilities, and opportunities for citizens and residents of the U.S. Since that time, the Congress has developed legislation that upon enactment and implementation was intended to provide protection to U.S. consumers. The Federal Food, Drug, and Cosmetic Act (the "FFDCA"), 21 U.S.C. § 301 *et esq.* is such a law which applies various limitations to the articles that are identified and for which the authority of the federal government is limited to articles for which the principles of interstate commerce are applicable.

For articles of devices, the Medical Device Amendments of 1976 (P.L. 94-295) created a presumption of interstate commerce, 21 U.S.C. § 885, but neither this nor any other provision of the FFDCA extends beyond the borders of any state or territory. Nonetheless, for any device manufactured for import into the U.S., it has been recognized and generally accepted that such devices are to comply with requirements of the FFDCA and regulations that apply to devices in interstate commerce irrespective of whether such devices for their intended use are manufactured within or outside the borders of the U.S. and its territories.

However, there is no requirement in the FFDCA that would authorize access by the Food and Drug Administration ("FDA") or any other agency of the U.S. government to any information relating to any device that is neither imported nor intended for import into any U.S. state or territory. As a result, the FDA has no right to obtain any information about such device either through inquiry or during inspection of any facility manufacturing such devices outside any U.S. state or territory.

Additionally, the FDA has no authority under the FFDCA to restrict import of the same or similar device into the U.S.; because, the manufacturer declines to provide information about any "non interstate commerce" device. The undersigned seeks confirmation of this fact based on the explanation of law that follows.

There is no published court opinion that confirms any authority for the FDA to access documents relating to articles that are neither offered for nor introduced into interstate commerce. Examination of U.S. statutes and opinions of the Federal Judiciary indicate that statutes presumptively govern only conduct in the U.S. unless Congress explicitly mandates extraterritorial application. *See K-S Pharmacies, Inc. v. American Home Products Corp.*, 962 F.2d 728, 730 (7th Cir. 1992), citing *EEOC v. Arabian American Oil Co.*, 499 U.S. 244 (1991).[2]

Upon interpreting the FFDCA, the courts give effect to congressional intent that remedial legislation such as the FFDCA "be given a liberal construction consistent with the Act's overriding purpose to protect the public health." *Meserey v. United States*, 447 F.Supp. 548, 552 (D. Nev. 1977), quoting *United States v. An Article of Drug . . . Bacto-Unidisk*, 394 U.S. 784, 793 (1969).

Balanced against this liberal interpretation, however, is the Supreme Court's recognition that:

> The Federal Food, Drug, and Cosmetic Act is a detailed and thorough piece of legislation. Its treatment of many public health and food problems is quite specific, and of course it is the duty of the courts in construing it to be mindful of its approach in terms of draftsmanship. Here again, in our construction of this explicit Act, *we must be sensitive to what Congress has written, and recall that "It is for us to ascertain – neither to add nor subtract, neither to delete nor to distort."*

Fleming v. Florida Citrus Exchange, 358 U.S. 153, 166 (1958), quoting *Cases of Jam v. United States*, 340 U.S. 593 (1951) (emphasis added).

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[2] *See, e.g., Hartford Fire Insurance Company v. California*, 509 U.S. 764 (1993) (Sherman Act expresses Congress's explicit mandate of extraterritorial reach, in that it applies to: "Every contract . . . in restraint of trade or commerce among the several States, or with foreign nations").

Based on the above, express language in the FFDCA limits its applicability to devices manufactured within or imported into the U.S. The FFDCA, therefore, does not apply to devices that are not imported into the U.S.

However, the FFDCA does authorize the FDA to prescribe regulations that are applicable to devices that are in interstate commerce. For example, regulations have been finalized which require that the methods used in, and the facilities and controls used for, the manufacture of a device conform to good manufacturing practices. 21 U.S.C. § 360j(f)(1)(A). Such regulations appear in 21 C.F.R. Part 820 and state:

> The requirements in this part govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use.

21 C.F.R. 820.1(a)(1). Application of this Quality System ("QS")/Good Manufacturing Practice ("GMP") regulation is explicitly limited to finished devices that are "manufactured, imported, or offered for import in any State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico." *Id.* at (a)(2).

Although the QS/GMP regulation does address the application of 21 C.F.R. § 820.1(d) to foreign manufacturers who offer devices for import into the U.S., that regulation is limited by its terms to FDA inspection of a foreign device establishment "for purposes of determining compliance with this part [21 C.F.R. Part 820]." Compliance with Part 820 is, of course, subject to the interstate commerce limitations set forth above.

Moreover, there is no reference in this regulation to the effect of foreign country "blocking statutes." These statutes of foreign governments generally require the explicit permission of an authorized government official for a foreign government agent (*e.g.*, FDA) to access such foreign facilities and documents. However, the preamble to the QS/GMP regulation in comment 180 at p. 52637 of the Federal Register of October 7, 1996, Vol. 61, No. 195, does state:

> "if manufacturers want to import medical devices into the United States, then they must comply with applicable statutory and regulatory requirements, including part 820."

Again, as expressed above, such compliance would relate only to finished devices that are imported or offered for import into any state or territory.

Because FDA inspection of foreign facilities requires the permission of the foreign manufacturer and the laws/policies of foreign governments require FDA recognition of matters relating to diplomacy, the FDA for years has maintained a "Guide to International Inspection and Travel." The Guide expresses standard operational,

inspectional, and investigational procedures. Consistent with the underlying mandate of the Act and applicable regulations, the Guide explicitly directs that:

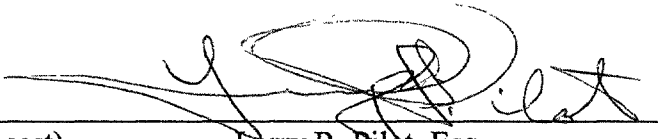
> "Only products . . . exported to the U.S. are covered during the . . ." establishment inspection.

See Guide at 402.1. The *Guide* further advises that enforcement action against a firm or product is administrative, such as Automatic Detention of a firm's products or regulatory action through seizure or recall of the product in the U.S.

Review of applicable U.S. statutes, regulations, and interpretations of law by Federal Courts, support that the FDA does not have authority to access information about and/or copy documents related to devices that are neither exported to nor intended for export into the U.S. Moreover, there is no legal precedent to support FDA refusal to permit import of devices based on a foreign manufacturer's denial to produce documents (*e.g.*, distribution records, complaints, etc.) relating to manufactured finished devices neither intended for nor distributed to the U.S.

For the reasons of fact and law described above, the undersigned seeks prompt issuance of an advisory opinion confirming the statement of issues appearing within the section "A. Issues Involved."

The undersigned certifies that, to the best of his knowledge and belief, this request includes all data, information, and views relevant to the matter, whether favorable or unfavorable to the position of the undersigned, which is the subject of the request.

(Signature) 

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